

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN**

CARACO PHARMACEUTICAL
LABORATORIES, LTD. AND SUN
PHARMACEUTICALS, LTD.,

Plaintiffs,

V.

NOVO NORDISK A/S AND NOVO
NORDISK, INC.,

Defendants.

Case No. _____

COMPLAINT

Plaintiffs Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceuticals, Ltd. hereby state the following claims for relief against Defendants Novo Nordisk A/S and Novo Nordisk, Inc. (together, “Novo”):

NATURE OF THE ACTION

1. This is an action for breach of contract based on a failure by Novo to perform as required by the Stipulation and Agreement Regarding Trial and Appeal executed by the parties on October 14, 2009 (“Agreement”) in connection with *Novo Nordisk A/S and Novo Nordisk, Inc. v. Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd.*, Case No. 2:05-CV-40188 (“Patent Case”), presided over by Judge Avern Cohn in this District.¹ Novo filed the Patent Case under the Hatch-Waxman Act, and that case pertained to Caraco’s effort to launch a generic version of Novo’s diabetes pharmaceutical product branded as Prandin® (repaglinide).

¹ The Agreement is not attached to this Complaint because certain terms are confidential. A copy of the Agreement is in possession of the Defendants, and Plaintiffs are willing to submit a redacted version or a version under seal.

PARTIES

2. Plaintiff Caraco Pharmaceutical Laboratories, Ltd. (“Caraco”) is a Michigan corporation having its principal place of business at 1150 Elijha McCoy Drive, Detroit, Michigan.

3. Plaintiff Sun Pharmaceutical Industries, Ltd. (“Sun”) is a company organized and existing under the laws of India, with a place of business at Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai-400 059, India.

4. Upon information and belief, Defendant Novo Nordisk A/S is a Danish corporation having a place of business at Novo Allé, DK-2880 Bagsvaerd, Denmark.

5. Upon information and belief, Defendant Novo Nordisk Inc. is a Delaware corporation having a place of business at 100 College Road West, Princeton, New Jersey.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1332 because the parties are diverse and the amount in controversy exceeds \$75,000.

7. This Court has personal jurisdiction over Novo because Novo has purposely availed itself of this forum in a related action against Caraco, *Novo Nordisk A/S and Novo Nordisk, Inc. v. Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd.*, Case No. 2:05-CV-40188. This suit arises from the Agreement, which the parties executed as related to and during the course of that case. Also, as part of its pharmaceutical business, upon information and belief, Novo regularly conducts sales within the State of Michigan.

8. Venue is proper in the United States District Court for the Eastern District of Michigan under 28 U.S.C. § 1391.

BACKGROUND

9. On or about May 6, 2009, Novo caused the U.S. Food and Drug Administration to change the “use code” narrative pertaining to U.S. Patent No. 6,677,358 for Prandin in a manner that did not accurately characterize the patent. This tactic by Novo blocked Caraco’s ability to obtain approval for its generic product under “section viii” of the Hatch-Waxman Act.

10. In the Patent Case, Caraco moved the Court to enter an injunction under the Hatch-Waxman Act requiring Novo to “correct” its use code. On September 25, 2009, this Court entered a permanent injunction requiring, among other things, Novo to “correct within twenty (20) days from the date of this Order and Injunction its inaccurate description of the ’358 patent by reinstat[ing] its former U-546 listing for Prandin.”

11. On September 29, 2009, Novo appealed this injunction to the United States Court of Appeals for the Federal Circuit (“Use Code Injunction appeal”). In that appeal, Novo argued: (a) “the Hatch-Waxman counterclaim does not authorize an order compelling Novo to change its use code narrative”; and, alternatively, (b) “Novo’s [then-]current use code narrative correctly track[ed] the approved indication.”

12. On October 14, 2009, the parties entered into the Agreement. Paragraph 5 of the Agreement states, in relevant part, that “Novo will pay Caraco’s outside counsel legal fees and costs for this case if Caraco prevails on the Use Code Injunction appeal in an amount of \$2.75 million, as a full compromise and settlement for any claim Caraco could make for such fees and costs, with payment to be made within thirty (30) days of a final Federal Circuit affirmance of the Use Code Injunction order.”

13. On April 14, 2010, a Federal Circuit panel reversed the injunction, holding that “the Hatch-Waxman Act authorizes a counterclaim only if the listed patent does not claim any

approved methods of using the listed drug.” But Caraco and Sun appealed that ruling to the United States Supreme Court.

14. On April 17, 2012, the Supreme Court reversed the Federal Circuit’s decision, holding that “Caraco may bring a counterclaim seeking to ‘correct’ Novo’s use code ‘on the ground that’ the ’358 patent ‘does not claim . . . an approved method of using the drug’—indeed, does not claim two.” The Supreme Court remanded the case to the Court of Appeals for further proceedings.

15. On July 30, 2012, in Case No. 2010-1001, the Federal Circuit issued its final ruling in the Use Code Injunction appeal, which found the use code incorrect and held:

Novo Nordisk is hereby directed by mandatory injunction under 21 U.S.C. § 355(j)(5)(C)(ii)(1)(bb) to correct within twenty (20) days from the date of this Order and Injunction its inaccurate description of the ’358 patent by submitting to FDA an amended form FDA 3542 for Prandin that accurately describes the scope of claim 4 of the ’358 patent in section 4.2b. The description shall be clearly limited to use of repaglinide in combination with metformin to treat non-insulin dependent diabetes mellitus.

16. On August 21, 2012, Novo did, in fact, correct its use code as ordered to do so by the Federal Circuit.

17. Caraco thus prevailed on the Use Code Injunction appeal.

18. Pursuant to paragraph 5 of the Agreement, Novo is required to pay Caraco the \$2.75 million within 30 days of this final Federal Circuit affirmance, i.e., by August 29, 2012.

19. Caraco has demanded such payment, but Novo has refused to make that payment. On August 28, 2012, Novo informed Caraco (through counsel) that it did not “agree that the Federal Circuit’s order can possibly be viewed as an ‘affirmance’ of the Use Code injunction order[.]”

COUNT 1: BREACH OF CONTRACT

20. Caraco incorporates paragraphs 1-19 by reference.

21. Caraco and Novo entered into the Agreement on October 14, 2009. The Agreement is valid and enforceable.

22. Paragraph 5 of the Agreement requires Novo to pay Caraco \$2.75 million within 30 days of the final Federal Circuit's affirmance of the Use Code Injunction order.

23. According to this provision, Novo is required to pay the specified amount to Caraco on or before August 29, 2012.

24. Novo has repudiated its obligation under the Agreement to pay Caraco the specified amount and has otherwise breached the Agreement.

25. Novo's breach caused, is causing, and will cause financial injury to Caraco.

PRAYER FOR RELIEF

WHEREFORE, Caraco prays for judgment from this Court against Novo and respectfully request the following relief:

- a. A judgment that Novo has breached paragraph 5 of the Agreement;
- b. An award of damages in the amount specified in the Agreement, or such other amount as the Court deems just and appropriate;
- c. Costs and expenses in this action;
- d. Such other and further relief as the Court deems just and appropriate.

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Dated: August 29, 2012

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